

## **RESPONSE TO OFFICE ACTION**

### **A. Status of the Claims**

Claims 1-55 were pending and claims 12-13, 15-27, and 33-34 were under examination in view of the present Action. Claims 1-11, 14, 28-32, and 35-55 were withdrawn in view of the Restriction Requirement dated October 1, 2007. As noted below, it is requested that claims 28-30 also be acknowledged as being linked to claim 12. Claims 12, 15, 17-20, 24, and 33-34 are amended to expedite prosecution and to more clearly claim the Applicants' invention. Support for the amendment of claims 12, 15, and 17-19 is found in the Specification, for instance at page 2, lines 31-32; page 6, lines 1-3; page 15, lines 1-2; page 15, lines 16-22; and page 29, lines 10-12. Claim 16 is canceled without prejudice in view of the amendment of claim 12. Claim 20 is amended in view of the amendment of claim 12. Claims 26-27 are canceled without prejudice. No new matter has been added. Thus, claims 12-13, 15, 17-25, 28-30, and 33-34 are presented herein for reconsideration.

### **B. Status of Election/Restriction Requirement**

The Office has previously acknowledged Applicant's election of Group III (claim 15). Applicants note that again in this Action claims 28-30 are apparently withdrawn as drawn to a non-elected group or species, in spite of the previous Action's acknowledgement, for instance, that claim 12 was considered as a linking claim. Applicants note that claims 28-30 depend ultimately on claim 12 and include all of its limitations. Applicants thus respectfully again request that claims 28-30 also be acknowledged as being linked by claim 12, and be examined upon allowability of claim 12.

### C. Claims Rejections Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 12, 13, 15-27, 33, and 34 under 35 U.S.C. § 112, first paragraph, as failing to comply with the Enablement Requirement. Applicants respectfully traverse in part, and note that claims 12, and 15, 17-20, 24, and 33-34 are amended herein.

Applicants note that the Action acknowledges that the claims are enabled for a formulation of glycinin and/or  $\beta$ -conglycinin as well as isolated soy material and isolated oil body associated protein (*e.g.* oleosin). Additionally, in order to expedite prosecution, the claims have been amended without prejudice, and no longer recite the terms “synergistic,” “fragment,” or “treating or preventing hypercholesterolemia.” The term “oil body associated protein” has been replaced by “oleosin.” As noted in the previous response, the Specification provides clear guidance for one of skill in the art to combine soy fractions with oleosin to lower cholesterol levels. For instance, the Specification at Example 2B and in FIG. 10 shows dose dependent inhibition of absorption of cholesterol by Caco-2 cells in the presence of a “HMF” fraction of peptides prepared from SPI enriched with oil body associated proteins (“HMF OBAP+”). When the cells are cultured in the presence of unhydrolyzed soy protein isolate enriched in oil body associated proteins (“SPI OBAP+”), no dose dependent inhibition was found demonstrating that the high molecular weight peptide fraction is required. Furthermore, no dose inhibition was possible from hydrolyzed SPI lacking OBAP because upon digestion with pepsin, no “HMF” fraction was generated (Example 4, page 43, line 26), demonstrating that OBAP is required to retain high molecular weight peptides during digestion of the soy proteins by pepsin. Further, Examples 4-5 indicate that the yield of the active cholesterol-lowering fraction (“HMF”) was increased under conditions that allow for retention of oleosins and phospholipids relative to the result obtained when HMF was extracted with

ethanol (*e.g.* Example 5). Thus the enablement rejection is believed to be moot, and its withdrawal is respectfully requested.

**D. Claims Rejections Under 35 U.S.C. § 102(b)**

The Action rejects claims 12, 13, 15, 20, 21, 26, 27, 33, and 34 under 35 U.S.C. § 102(b) as being anticipated by Bringe (U.S. Patent 6,171,640). Bringe is asserted to disclose a composition comprising high  $\beta$ -conglycinin and/or glycinin in combination with oil body associated protein. Applicants respectfully note that the claims have been amended or canceled as indicated above.

In particular, it is known in the art that about 2-3% of total soybean seed protein comprises oil body associated proteins such as oleosins (*e.g.* Kalinski *et al.*, *J. Biol. Chem.* 265:13843-13848, 1990; 1<sup>st</sup> full paragraph in right column on page 13847). Applicants note that claim 12 now recites that the composition comprises at least 5% oleosin. The cited '640 reference does not teach or suggest augmenting the oleosin content of a soy composition, for instance to reach a level of 5% or greater of oleosin. In view of this, the anticipation rejection is believed to be moot, and its withdrawal is respectfully requested.

**E. Claims Rejections Under 35 U.S.C. § 103(a)**

The Action rejects claims 12, 13, 15-27, 33, and 34 as being unpatentable over Bringe (U.S. Patent 6,171,640), citing Kelly (U. S. Patent 5,830,887), Fiordaliso (*Lipids* 30:163-167, 1995) and Hori (*Biosci. Biochem.* 65:72-78, 2001) regarding certain claims. Applicants respectfully traverse in part, while again noting that the claims have been revised to state that the claimed composition comprises at least 5% oleosin.

**I. The Cited Reference Teaches Away From the Asserted Combination.**

The Action asserts that the claims are obvious over Bringe (U.S. Patent 6,171,640), although additional references or reasoning at least relating to alleged obviousness of claim 12 are apparently

not provided (see below, sections 3-4). The Action asserts that Bringe (columns 7, 11, 16, and 18) discloses a composition comprising high  $\beta$ -conglycinin and/or glycinin in combination with oil body associated protein, that  $\beta$ -conglycinin is a glycoprotein that may be hydrolyzed, and also discusses further additives including egg yolk lipoprotein, egg white, isoflavin (sic; isoflavone?) (Action, page 11 last paragraph; as referred to at Action, page 14, 2<sup>nd</sup> full paragraph). As an initial matter, Applicants respectfully note that column 11 of the '640 patent does not disclose adding egg white to a soy protein isolate. Instead, it compares the gelling properties of a high BC-SPI composition with those of egg white. Since the relatively less expensive high BC-SPI displays a viscosity approaching that of egg white, the '640 Specification thus *teaches away* from adding egg white to a SPI, instead teaching that BC-SPI may be *substituted for* egg white or used instead of egg white while achieving certain food processing properties. Likewise, at column 7, *e.g.* lines 36-52, the '640 Specification is contemplating *substitution* of, for instance, lipoproteins in egg yolk with high BC-SPI compositions for certain food processing applications, because of the emulsifying and viscoelastic properties of BC-SPI. Again, this *teaches away from the asserted combination*. Further, while  $\beta$ -conglycinin is stated to be a glycoprotein at column 16, line 26, this is in no way relevant to the claimed addition of additional distinct carbohydrates as found in claim 23. Thus, withdrawal of the rejection is respectfully requested.

**2. No Prima Facie Case for Obviousness of Claims 12, 13, 15, 33, and 34 Has Been Provided.**

Applicants also note that the obviousness rejection does not provide any arguments regarding rejection of claims 12, 13, 15, 33, and 34. That is, no references are apparently combined with '640 to result in the obviousness rejection of these claims, and no other reasoning is provided. Thus the rejection is apparently more properly an anticipation rejection, as is indeed stated in the

Action at page 14, first full paragraph (“Claims...rejected under 35 U.S.C. 102(b)...”), which however disagrees with the title of the section as found on page 13. If it is the case that an anticipation rejection under 35 U.S.C. § 102(b) is being made, Applicants respectfully direct the Examiner’s attention to section D above, and submit that the rejection in view of ’640 alone is now moot. If however an obviousness rejection is meant, Applicants respectfully request that this be clarified, and that a combination of references supporting such an assertion be provided, so that a meaningful response may be made. Alternatively, the rejection is submitted to be moot in view of the current amendments to the claims. Finally, if “common knowledge” is being asserted for instance against claim 12 in combination with ’640, Applicants respectfully submit that the rejection is conclusory and based on hindsight. No reasoning is provided to support the rejection. M.P.E.P. 2144 (I) states that such reasoning must be provided (“Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection)...,” while M.P.E.P. 2144.03 states that “official notice” of a factual assertion of “common knowledge” must be provided. Thus, Applicants respectfully request that, if necessary, such notice be provided on the record, including evidentiary support and reasoning (M.P.E.P. 2144.03 (C)), so that an appropriate response may be made. In particular, applicants submit that evidence for teachings or reasoning regarding augmentation of oleosin content, as currently claimed, is lacking.

### **3. Obviousness Rejections of claims 16-24**

At any rate, at least regarding claims 20-24, the Action apparently cites Kelly as disclosing compositions enriched in phytoestrogens such as isoflavones (*e.g.* claim 22); Fiordaliso is cited regarding adding a carbohydrate (oligofructose) to a diet (*e.g.* claim 23); and Hori is cited as allegedly teaching addition of phospholipid such as lecithin to vegetable protein (*e.g.* claim 24). Applicants note that none of these references relate to adding oleosin to a soy protein composition,

as is presently claimed. Applicants also respectfully note that claims 20-24 ultimately depend from claim 12. Thus, if claim 12 is non-obvious, then claims 20-24 must also be non-obvious ("If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." M.P.E.P. 2143.03 All Claim Limitations Must Be ~~Be~~ Considered [R-6], citing In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Applicants further respectfully submit that no *prima facie* case for the obviousness of claim 12 has been made, since no references are combined with '640 under 35 U.S.C. § 103(a) with respect to claim 12, and no further reasoning for rejection of claim 12 as obvious is provided. Thus, withdrawal of the rejection of claims 20-24 as obvious is respectfully requested.

At page 16, regarding claims 16-19, the Action states that '640 at column 9 refers to various percentages of oil body associated proteins, and a skilled worker would know how to optimize the necessary amount. Applicants submit that the rejection of claim 16 is moot in view of its cancellation. Applicants respectfully traverse in part as follows, while noting, as above, that claims 17-19 depend from claim 12, and further that claim 12 has been amended in the present response.

No *prima facie* case for obviousness of claim 12 has been provided (also see above). If claim 12 is non-obvious, then claims 17-19 must also be non-obvious ("If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." M.P.E.P. 2143.03 All Claim Limitations Must Be ~~Be~~ Considered [R-6], citing In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). A careful review of the '640 specification also indicates that column 9 as cited in the Action describes certain contemplated ranges of percentages for glycinin and/or  $\beta$ -conglycinin (or subunits thereof) content. However, no mention is made of, for instance, a range of oleosin content as is presently claimed. Neither is there contemplated any augmentation of

the oleosin content of a soy protein composition. In view of the amendment of claim 12, Applicants submit that the rejection of claims 17-19 is now moot and its withdrawal is respectfully requested.

Additionally, no specific reference in addition to '640 is cited in connection with the apparent obviousness rejection of claims 17-19. Thus Applicants respectfully submit that the obviousness rejection is improper. Alternatively, if the Action is asserting that the general knowledge of a skilled worker may be combined with the single cited reference, Applicants respectfully submit that the rejection is conclusory and based on hindsight. No reasoning is provided to support the rejection, let alone a rejection of these claims as presently amended. M.P.E.P. 2144 (I) states that such reasoning must be provided ("Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection)...," while M.P.E.P. 2144.03 states that "official notice" of a factual assertion of "common knowledge" must be provided. Thus, Applicants respectfully request that such notice be provided on the record, including evidentiary support and reasoning (M.P.E.P. 2144.03 (C)), so that an appropriate response may be made. In particular, applicants submit that evidence for teachings or reasoning regarding augmentation of oleosin content, as currently claimed, is lacking. In the absence of this, withdrawal of the rejection is respectfully requested.

#### **F. Conclusion**

In view of the above, it is submitted that all of the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned at (214) 259-0931 with any questions, comments, or suggestions relating to the referenced patent application.

Respectfully submitted,

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